UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address : COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/982,130	11/25/92	M IZUMI	M 3496.0010-02

EXAMINER
BAILEY

18062

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER
1300 I ST, NW
WASHINGTON, DC 20005-3315

ART UNIT	PAPER NUMBER
1804	7

DATE MAILED: 07/30/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☒ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 11 AND 12 are pending in the application.
   Of the above, claims 12 is/are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 11 is/are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☒ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☒ not been received ☒ been filed in parent application, serial no. 07/982,130 ; filed on _____. U.K. 84 29099 FRANCE 84 16013
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 13 is rejected under 35 U.S.C. § 101 because the invention as claimed lacks patentable utility and as disclosed is inoperative. This rejection is maintained for reasons given in the previous office action, paper No. 7, mailed 30 July 1993.

The previous office action held:

> Applicant claims nucleotide sequences from HIV-1. In particular, applicant cites for support the specification page 3, line 35 through page 4, line 3; page 7, lines 18-26; page 12, line 29 through page 13, line 18; and page 15, lines 18-21. These citations do set forth what is being claimed, but does not demonstrate a utility for these nucleotide sequences. On page 14, lines 11-19 the disclosure holds that DNA can be used for "cloned probes". In addition, page 15, lines 18-24, notes of "polypeptides themselves which can be expressed by the different DNAs of the instant inventions, particularly by the ORFs or fragments thereof."
>
> Applicant has not demonstrated a utility for these sequences as probes. How specific are they for detecting HIV and distinguishing it from other retroviruses, in particular HTLV I and II? Applicant has not demonstrated that these sequences function to have the utility as described.
>
> Also, applicant notes in the specification, in particular Figures 2 and 3, that the nucleic acids claimed are "ORFs." Applicant believes that the nucleic acid sequences claimed are translatable into proteins having distinct sequences, such protein thereby having various utilities as stated in the specification. However, applicant has not demonstrated that these nucleic acid sequences comprising these "ORFs" are indeed translated into proteins having a demonstrable

> utility. Therefore, the nucleic acids as claimed have no demonstrated utility.

Applicant's arguments filed 24 November 1993 and 15 February 1994 have been fully considered but they are not deemed to be persuasive. In response to applicant's arguments, it is noted that applicant simply locates an open reading frame in the sequence of the clone of the instant application. The specification does not show a utility for any protein supposedly expressed from this open reading frame. Nor does applicant demonstrated a utility for this nucleic acid sequence as a probe. As noted in the reference by Wain-Hobson et al. [Cell 40:9-17 (1985)] on page 14:

> The function for the putative proteins pQ and pF cannot be predicted...

Applicant does not demonstrate expression of any protein encoded by the nucleic acid sequence as claimed. Successful expression of cloned genes in a heterologous expression system requires the consideration and balance of many factors. See Brown et al. [U.S. Patent 5,001,230], columns 3 and 4, for example. Applicant has not provided proper guidance regarding how to effect successful expression of the open reading frame as disclosed. Without successful expression of the open reading frame, a specific patentable use of such a protein has not been established. Use of such a protein as a diagnostic, immunogen or vaccine is not established in the specification as filed.

Do patients produce specific antibodies to the protein, the presence of such antibodies being consistently detectable using the expressed protein as a diagnostic? Is the protein indeed "immunogenic" for the generation of antibodies useful in diagnostic assays? Is the protein useful as a vaccine? None of this is established in the specification as filed. Neither does applicant set forth the conditions under which the nucleic acid would serve as a specific probe having a demonstrable utility. As the nucleic acid sequence claimed overlaps with the 3'LTR, it has not been demonstrated under what conditions the nucleic acid sequence would serve as a probe specific for HIV. Applicant is provided with a reference by Hahn et al. [Nature 312:166-169 (1984)]. Figure 4 notes that when HIV is used as a probe, under certain conditions of hybridization, the LTR region of HtLV-1 appears to cross-hybridize. It is not apparent in the specification as filed that specific conditions have been set forth which would allow the use of the claimed nucleic acid sequences as a specific probe with a demonstrable utility.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION

IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. F. Railey whose telephone number is (703) 308-0281.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C Weimar

ELIZABETH C. WEIMAR
SUPERVISORY PATENT EXAMINER
GROUP 180

Johnny F. Railey II, Ph.D.
April 17, 1994